

### REMARKS

Applicants have carefully reviewed and considered the Office Action mailed on September 9, 2003, and the references cited therewith. In response, Applicants have amended claims 24 and 35 to remove a duplicated phrase and a parenthetical term. In addition, Applicants have amended claim 31 to correct a punctuation error. Further, claim 22 has been amended to recite a method for modulating vascular tone in a patient having compromised vascular tissue associated with erectile dysfunction. Support for this amendment can be found in Applicants' specification at page 11, lines 16-21, and in claim 30, which has been canceled in light of the amendment to claim 22. Claim 33 has been amended to recite a method for modulating penile vascular tone in a mammal in need thereof. Support for this amendment can be found in Applicants' specification at, for example, page 10, lines 8-12.

Applicants would like to draw the Examiner's attention the fact that the Attorney Docket No. has been changed to 17023-017001. No new matter has been added.

In light of these amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claims 22-24, 27-29, 31-35, and 38-42.

### Objections to the Claims

The Examiner objected to claims 24 and 35 due to various informalities. Applicants have amended claim 24 to remove the duplication of the term "wherein the." Applicants also have amended claims 24 and 35 to remove the term "(tamoxifen)." In light of these amendments, Applicants respectfully request withdrawal of the objection to claims 24 and 35.

### Rejections under 35 U.S.C. § 102

The Examiner rejected claims 22-24, 27-29, 32-35 and 38-42 under 35 USC § 102(b) as being anticipated by Stromberg (U.S. Patent No. 5,470,883). The Examiner stated that the Stromberg reference teaches a method of using tamoxifen to inhibit or reverse peripheral vasoconstriction caused by an adrenergic agent such as epinephrine or norepinephrine. The Examiner further alleged that the effect of tamoxifen on a particular site (e.g., as recited in present claims 33 and 41-42) would be inherent upon administration of tamoxifen to reverse vasoconstriction caused by norepinephrine as taught by the Stromberg reference.

Applicants respectfully disagree. To anticipate a claim, a reference must teach every element of the claim. MPEP § 2131. Moreover, the court in *In re Newell* stated that “[A] retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in the particular claimed combination.” *In re Newell*, 891 F.2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989).

Independent claim 22 as amended recites a method for modulating vascular tone in a patient having compromised vascular tissue associated with erectile dysfunction. Independent claim 33 as amended recites a method for modulating penile vascular tone in a mammal in need thereof. Nowhere does the Stromberg patent disclose using a chloride channel blocking agent or a pharmaceutically acceptable salt thereof to modulate vascular tone in a patient having compromised vascular tissue associated with erectile dysfunction. Further, nowhere does the Stromberg patent disclose using a chloride channel blocking agent or a pharmaceutically acceptable salt thereof to modulate penile vascular tone in a mammal in need thereof. Thus, claims 22-24, 27-29, 32-35 and 38-42 are not anticipated by the Stromberg patent.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 22-24, 27-29, 32-35 and 38-42 under 35 U.S.C. § 102(b).

The Examiner rejected claims 22 and 30 under 35 USC § 102(b) as being anticipated by Grainger *et al.* (U.S. Patent No. 6,197,789). Specifically, the Examiner stated that the Grainger *et al.* reference teaches that tamoxifen is useful to inhibit pathological activity of vascular smooth muscle cells, and to inhibit the activation of endothelial cells associated with vascular surgery, diabetes, hypertension, and coronary artery blockage.

Applicants respectfully assert that the Grainger *et al.* reference is not available as art under 35 U.S.C. § 102(b). 35 U.S.C. § 102(b) states that a “person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of application for patent in the United States.” The Grainger *et al.* reference became publicly available less than one year prior to Applicant’s filing date. Therefore, the Grainger *et al.* reference does not meet the requirements of 35 U.S.C. § 102(b).

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 22 under 35 U.S.C. § 102(b).

Rejection under 35 U.S.C. § 103

The Examiner rejected claim 31 under 35 USC § 103(a) as being unpatentable over Grainger *et al.* (U.S. Patent No. 6,197,789). In particular, the Examiner stated that the Grainger *et al.* reference does not teach further administering the agents set forth in present claim 31, but that it would have been obvious to one of ordinary skill in the art to incorporate such agents together with tamoxifen for treating diabetes, hypertension, and coronary artery disease. The Examiner further alleged that "[o]ne would have been motivated to employ other agents set forth in claim 31 together with tamoxifen in order to achieve at least an additive effect in treatment of diseases well known to be treated by tamoxifen as well taught by Grainger *et al.*"

As stated above, the Grainger *et al.* reference is not available as art under 35 U.S.C. § 102(b). As such, this reference cannot be used to substantiate an obviousness rejection.

In light of the above, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

**CONCLUSION**

Applicants respectfully submit that claims 22-24, 27-29, 31-35, and 38-42 are in condition for allowance, which action is requested. The Examiner is invited to telephone the undersigned if such would further prosecution. Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 9 March 2004

Ann S. Viksnins  
Ann S. Viksnins, Reg. No. 37,748

Fish & Richardson P.C., P.A.  
60 South Sixth Street, Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696  
60198039.doc